FARNAN LLP

July 9, 2021

VIA E-FILING
The Honorable Colm F. Connolly
J. Caleb Boggs Federal Building
844 N. King Street
Room 4124, Unit 31
Wilmington, DE 19801-3555

RE: ***Par Pharmaceutical Inc., et al. v. Eagle Pharmaceuticals Inc.***
C.A. No. 18-cv-823-CFC-JLH

Dear Chief Judge Connolly,

We write in response to Defendants' letter of July 8, 2021 setting forth definitions for various types of specifications. As we advised Your Honor verbally, Par largely agrees with the definitions Defendants provided. We provide, however, the following additional commentary:

- **Release Specification:** We note that FDA regulations state, in particular, that "[f]or each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product . . . prior to release" and that products that fail to meet the release specifications "shall be rejected."' 21 CFR 211.165(a), (f). The converse is also true – drug products meeting those specifications may be released for commercial sale. *Id.*

- **Compounding pH:** To our knowledge, "compounding pH" is not a term of art that is defined in FDA regulations or elsewhere, but note that Eagle used it at various places in its Pretrial Order submissions (e.g., Exhibit 3). We don't know the source of Defendants' quotes, but generally understood Eagle to be referring to the intended pH of the bulk solution at various points during the compounding process that call for pH measurements or adjustments.

We are available at the Court's convenience should Your Honor have any questions.

Respectfully submitted,

/s/ Michael J. Farnan

Michael J. Farnan

cc: Counsel of Record (Via E-File)